

**WRIGHT**

MEDICAL TECHNOLOGY, INC.

5677 AIRLINE ROAD
ARLINGTON, TN 38002
901-867-9971

OCT - 2 1996

K963200

510(k) Summary

Contact Person: Cristie Manuel
Date Prepared: September 30, 1996

Trade/Proprietary Name: QUESTUSTTM Polyester Suture Soft Tissue Anchor System,
Size 7.5mm
Common Name: Fastener, fixation, nondegradable, soft tissue
Product Classification: Class II
Predicate Device: QUESTUSTTM Polyester Suture Soft Tissue Anchor System

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

Description/Intended Use

The QUESTUSTTM Polyester Suture Soft Tissue Anchor System, size 7.5mm, is a single use, sterile, preassembled kit consisting of a bone anchor, a suture, and a disposable instrument driver, and is an additional size offering to the QUESTUSTTM Polyester Suture Soft Tissue Anchor System. The anchor is manufactured from titanium alloy and threaded into bone. Soft tissue is secured to the implant site with suture.

The QUESTUSTTM Polyester Suture Soft Tissue Anchor System is indicated for the following:

- repair of shoulder instability secondary to Bankart lesion, rotator cuff tear, a SLAP lesion, acromioclavicular separation, biceps tenodesis, deltoid tear/separation, or capsular shift or capsulolabral reconstruction;
- repair of elbow instability secondary to biceps tendon detachment, tennis elbow, or ulnar or radial collateral ligament tear/separation;
- repair of hand/wrist instability secondary to tear or separation of the scapholunate ligament, ulnar collateral ligament, or radial collateral ligament;
- repair of knee instability secondary to tear or separation of the medial collateral ligament, lateral collateral ligament, patellar tendon, or posterior oblique ligament, or secondary to iliotibial band tenodesis;
- repair of foot/ankle instability secondary to tear or separation of the Achilles tendon, lateral stabilization tendons/ligaments; medial stabilization tendons/ligaments, midfoot tendons/ligaments, or metatarsal tendons/ligaments

Testing Summary

The 7.5mm QUESTUSTTM Polyester Suture Soft Tissue Anchor System was tested according to *Draft Guidance Document for Testing Bone Anchor Devices*, April 1, 1993. The conclusion from this test is that the 7.5mm anchor can be expected to meet or exceed the in vivo performance of the 5.0mm anchor.